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Porat

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(54) **KINK-RESISTANT GAS DELIVERY TUBE**

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PCT Pub. Date: **Jun. 14, 2012**

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(51) **Int. Cl.**

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A61M 25/14 (2006.01)
A61M 25/00 (2006.01)
A61M 39/08 (2006.01)

(52) **U.S. Cl.**

CPC ***A61M 16/0875*** (2013.01); ***A61M 25/0023*** (2013.01); ***A61M 39/08*** (2013.01); *A61M 2025/0059* (2013.01)

(58) **Field of Classification Search**

CPC A61M 25/005; A61M 25/0023; A61M 25/0032; A61M 2025/0059; A61M 39/08; A61M 16/0875; A61M 16/08; A61M 16/0666

USPC 138/108, 153, 159

See application file for complete search history.

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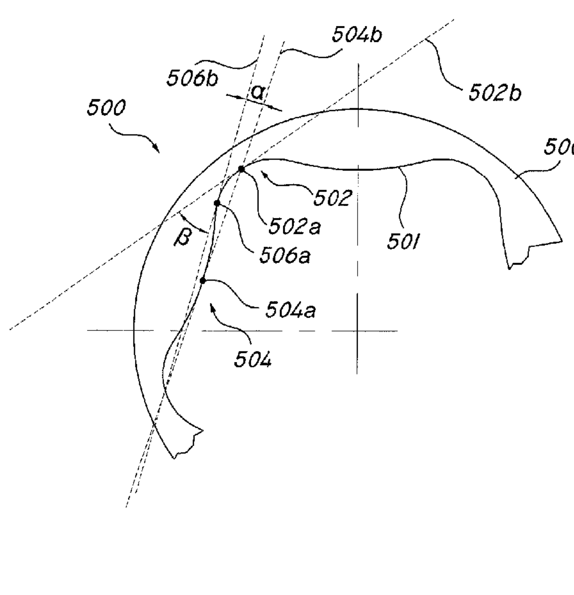
(57) **ABSTRACT**

A kink-resistant gas delivery tube configured to be directly connected to a circular male plug, the tube having an internal geometry of multiple concave and convex areas each having an apex, wherein an angle α between a tangent line to the apex of a concave area and a tangent line to a point of maximum slope between the apexes is 30 degrees or less, or wherein an angle β between a tangent line to the apex of a convex area and a tangent line to a point of maximum slope between the apexes is 30 degrees or less.

14 Claims, 3 Drawing Sheets



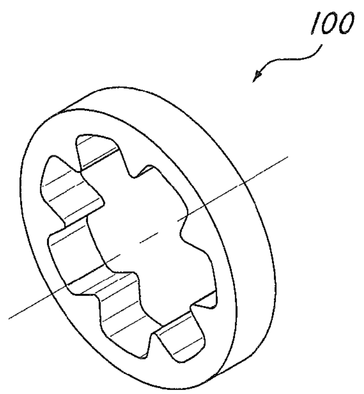


FIG. 1A
PRIOR ART

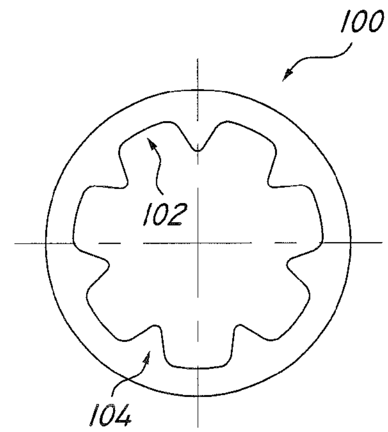


FIG. 1B
PRIOR ART

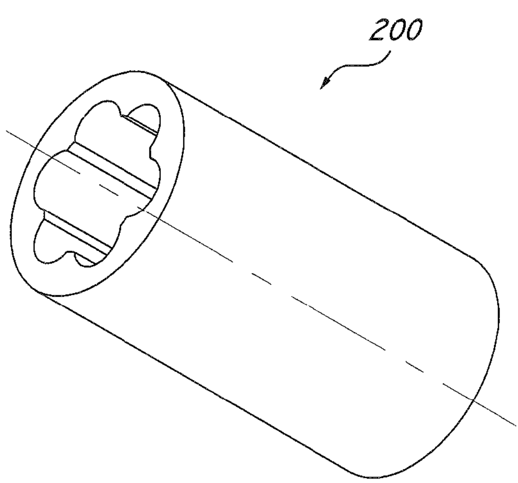


FIG. 2A
PRIOR ART

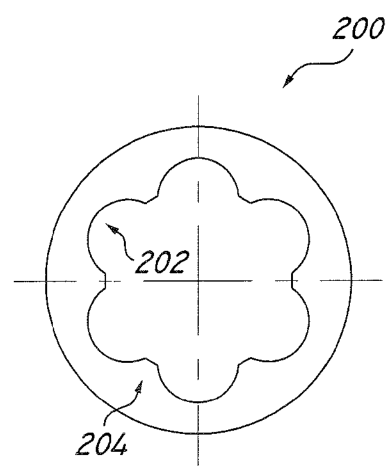


FIG. 2B
PRIOR ART

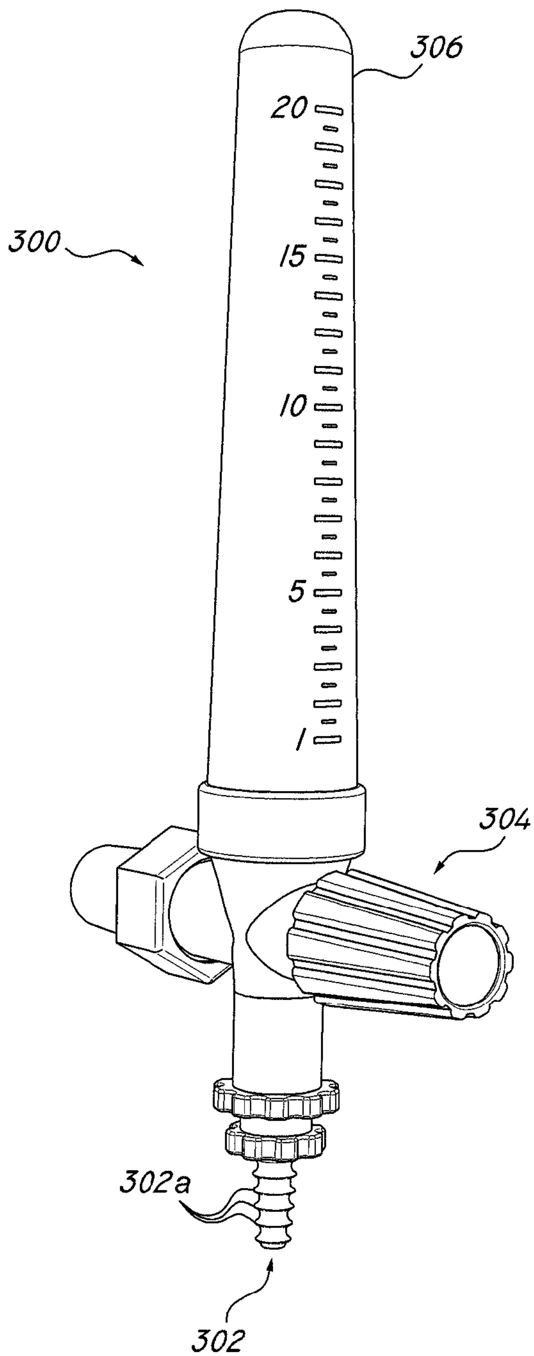


FIG. 3

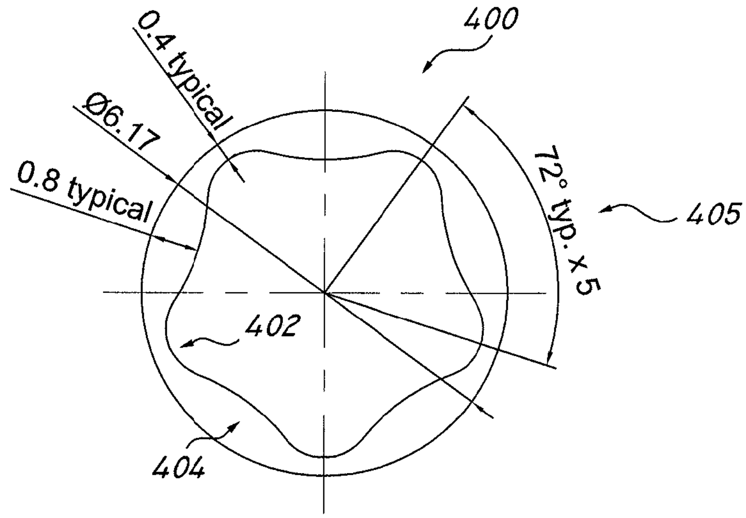

400
0.4 typical
Ø6.17
0.8 typical
72° typ. x 5
405
402
404

FIG. 4

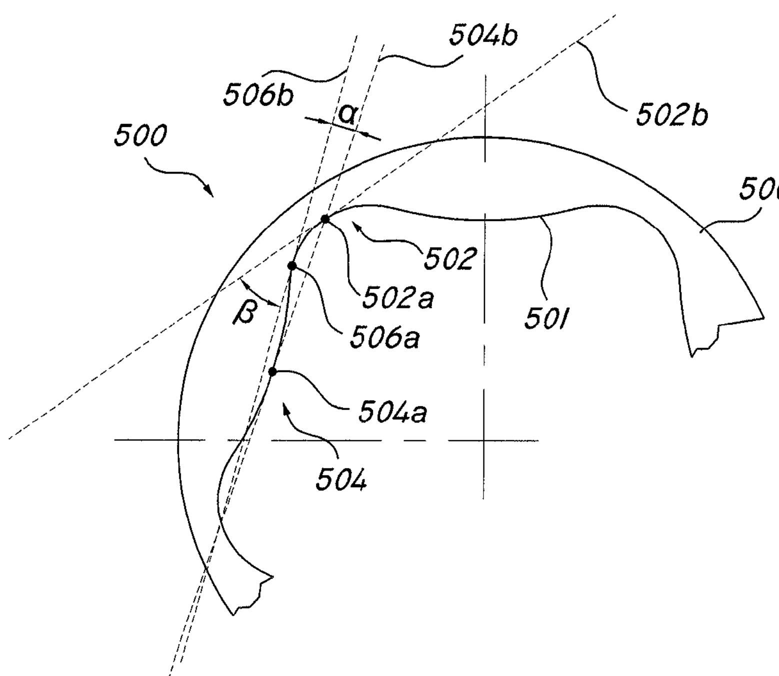

504b
506b
α
502b
500
500
502
502a
501
β
506a
504a
504

FIG. 5

KINK-RESISTANT GAS DELIVERY TUBE

RELATED APPLICATION DATA

This application is the U.S. National Stage of International Application No. PCT/IL2011/050046, filed Dec. 7, 2011, which claims the benefit of U.S. Provisional Application No. 61/421,233, filed Dec. 9, 2010, the contents of each of which are herein expressly incorporated by reference for all purposes.

FIELD OF THE INVENTION

An aspect of some embodiments relates to a kink-resistant gas delivery tube.

BACKGROUND OF THE INVENTION

Tubes, connectors, nipples and other types of equipment which are used in respiratory therapy are commonly subject to strict requirements, meant to ensure their suitability for medical use. Such equipment is often used for the supply of medicinal gasses, such as oxygen, to patients.

A number of standards, such as International Standard ISO 5356-1:2004, European Standard No. EN 13544-2:2002E, British Standard No. BS EN 13544-2:2002+A1:2009 (all three incorporated herein by reference in their entirety) and others, list numerous requirements which respiratory therapy equipment must comply with. One of the many requirements is kink-resistance. A tube used for the delivery of gas has to be highly reliable, to the degree it is still able to deliver at least some gas to the patient when folded, squashed or the like.

The foregoing examples of the related art and limitations related therewith are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a study of the figures.

SUMMARY OF THE INVENTION

The following embodiments and aspects thereof are described and illustrated in conjunction with systems, tools and methods which are meant to be exemplary and illustrative, not limiting in scope.

There is provided, in accordance with an embodiment, a kink-resistant gas delivery tube configured to be directly connected to a circular male plug, the tube having an internal geometry of multiple concave and convex areas each having an apex, wherein an angle α between a tangent line to the apex of a concave area and a tangent line to a point of maximum slope between the apexes is 30 degrees or less, or wherein an angle β between a tangent line to the apex of a convex area and a tangent line to a point of maximum slope between the apexes is 30 degrees or less.

In some embodiments, angle α is in the range of approximately 5-15 degrees.

In some embodiments, angle α is in the range of approximately 16-29 degrees.

In some embodiments, angle β is in the range of approximately 5-15 degrees.

In some embodiments, angle β is in the range of approximately 16-29 degrees.

In some embodiments, a ratio between angle α and angle β is in the range of approximately 1:1 to 1:4.5.

In some embodiments, a ratio between angle β and angle α is in the range of approximately 1:1 to 1:4.5.

There is provided, in accordance with an embodiment, a kink-resistant gas delivery tube configured to be directly connected to a circular male plug, the tube having an internal geometry of multiple concave and convex areas, wherein a ratio between a wall thickness of said tube at a concave area and a convex area is in the range of 1:1.25 to 1:3.

In some embodiments, said tube has an outer diameter of approximately 6 millimeters and a wall thickness of approximately 0.4 millimeters at a concave area and 0.8 millimeters at a convex area.

In some embodiments, said tube is made of soft PVC.

In some embodiments, said tube has a flow resistance of less than approximately 0.25 kPa/meter at a flow rate of 4 liters per minute.

In some embodiments, said tube has a flow resistance of approximately 0.11 kPa/meter at a flow rate of 4 liters per minute.

In some embodiments, said tube has a flow resistance of between approximately 0.07 and 0.15 kPa/meter at a flow rate of 4 liters per minute.

In some embodiments, said tube, when kinked, enables a flow rate of approximately 7.5 liters per minute or more with a resistance less than approximately 0.25 kPa/meter

In some embodiments, said tube, when kinked, enables a flow rate of approximately 10 liters per minute or more.

In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to the figures and by study of the following detailed description.

BRIEF DESCRIPTION OF THE FIGURES

Exemplary embodiments are illustrated in referenced figures. Dimensions of components and features shown in the figures are generally chosen for convenience and clarity of presentation and are not necessarily shown to scale. It is intended that the embodiments and figures disclosed herein are to be considered illustrative rather than restrictive. The figures are listed below.

FIG. **1**A shows a perspective view of a first exemplary tube geometry, according to the prior art;

FIG. **1**B shows a cross-sectional view of the first exemplary tube geometry, according to the prior art;

FIG. **2**A shows a perspective view of a second exemplary tube geometry, according to the prior art;

FIG. **2**B shows a cross-sectional view of the second exemplary tube geometry, according to the prior art;

FIG. **3** shows a semi-pictorial view of a gas regulator, according to the prior art;

FIG. **4** shows a cross-sectional view of the tube geometry; and

FIG. **5** shows an enlarged portion of the cross-sectional view of the tube geometry.

DETAILED DESCRIPTION

An aspect of some embodiments relates to a gas delivery tube having a geometry and made from such material which advantageously cause it to be both kink-resistant and suitable for connection to a circular male plug. Such a tube may be especially beneficial in the delivery of a medicinal gas, commonly oxygen, to a patient.

As described above, the need for the kink-resistance capability of gas delivery tubes stems mainly from the desire to supply gas to the patient in a highly reliable manner. FIGS. **1**A-B and **2**A-B show exemplary prior art kink-resistant tubes. Referring now to FIG. **1**A, a tube **100** having what is often called a "star" geometry is shown in perspective. FIG. 1B shows a cross sectional view of the same tube **100**, with its concavities **102** and convexities **104** more clearly visible. By virtue of this "star" geometry, when tube **100** is folded or when another external force is exerted on it, some space is still maintained between one or more opposing concavities **102** and/or convexities **104**, allowing for passage of at least some of the gas.

FIG. **2**A shows another exemplary prior art kink-resistant tube **200**. Tube **200**, shown in perspective, demonstrates an additional kink-resistant geometry. In FIG. **2**B, concavities **202** of tube **200** are essentially round, while convexities **204** are straight areas between the concavities.

Kink-resistant tubes, naturally, have to be connected to a gas source at one end, and to a patient interface (such as a mask, a nasal cannula and/or the like) at the other end. The connection to these features is often made using circular male plugs (or "nipples") that exist at the gas source and/or at the patient interface. However, the internal concavity-convexity geometry of prior art tubes often makes it inefficient to connect them directly to the gas source and the patient interface; this geometry does not provide for a gas-tight connection, since essentially only the convexities of the geometry are able to contact the circular male plug, and therefore gas can escape in the grooves formed between plug and the concavities. Hence, special adapters are usually used to mediate between the concave-convex tube and the gas source and/or the patient interface. Such adapters usually match the outer diameter of the tube geometry on one side, and have a circular geometry on the other side. They are commonly being glued to one or both ends of the tube.

Despite the fact that the adapters often provide a reasonable solution to the problem of connecting a tube, such as a kink-resistant tube, to gas supply and/or to a patient interface, this is not a sufficient solution for all scenarios. Many times, during the course of medical treatment of a patient, the gas delivery tube being used is determined to be too long. Then, the tube has to be discarded and replaced by a new, shorter one. It would be advantageous to provide a gas delivery tube which is both kink-resistant and configured to be directly and tightly connected to a male plug, so as to both eliminate the need for adapters and allow the tube to be efficiently shortened by way of cutting it (using scissors, for example) and re-connecting the new end to the patient interface or the gas supply nipple without producing a leak at the connector and risk to the patient.

Another scenario in which usage of a gas delivery tube which is both kink-resistant and configured to be directly and tightly connected to a male plug may be advantageous, is when a kink-resistant tube is connected, at the patient's end, to a low flow patient interface such as a nasal cannula (which commonly supplies up to approximately 5 liters per minute, but may nonetheless supply a higher or lower volume). Then, an urgent need might arise to significantly increase the oxygen supply, by switching to a facial mask adapted to deliver, typically, up to about 15 liters per minute, but may deliver a higher or a lower amount of gas per minute. The present, advantageous design may allow the caregiver to cut the tube close to the nasal cannula and connect it immediately to a face mask, without disconnecting the tube from the gas supply nipple of the regulator.

Reference is now made to FIG. **3**, which shows a semi-pictorial view of a gas regulator **300**, according to the prior art. Gas regulator **300** may include a flow meter **306**, shown here, merely as an example, as a traditional Thorpe tube controlled by a rotating knob **304**. However, other types of flow meters exist, such as electronic flow meters and others. Gas is provided by gas regulator **300** through a nipple **302**, which is often constructed as a male plug having a plurality of bulging rings **302***a* on its outer surface, for the purpose of enhancing the gas-tight seal between the nipple and the adapter mounted onto it.

Reference is now made to FIG. **4**, which shows a cross-sectional view of a kink-resistant gas delivery tube **400**, according to an embodiment. Advantageously, tube **400** may be constructed in such a way that it may be both kink-resistant (optionally in compliance with one or more of the pertinent standards, such as those referenced in the background section above) and directly connectable to a circular nipple of a gas regulator (such as nipple **302** of FIG. **3**), while forming an essentially gas-tight seal.

An additional advantage of tube **400** is its low resistance to flow (optionally in compliance with one or more of the previously-mentioned standards), resulting from its relaxed inner configuration and/or its relatively low inner surface area; again, this virtue of the tube is achieved, advantageously, while not significantly compromising its kink-resistibility and its direct connectivity to the gas regulator nipple.

In an embodiment, tube **400** may include a relaxed concave-convex configuration. Tube **400** may include, in its internal geometry, a plurality of concave areas (hereinafter "concavities") **402** and a plurality of convex areas (hereinafter "convexities") **404** arranged in a parabolic shape. As an example, five concavities **402** and five convexities **404** are shown, each concavity-convexity pair spreading over 72 degrees **405**, but a different number of these features is explicitly intended herein.

The relaxed concave-convex configuration may be expressed in one or more parameters:

A first parameter may be, for example, a relatively small angular difference between each of the apexes of concavities **402** and convexities **404**, and the slope between these apexes. Reference is now made to FIG. **5**, which shows an enlarged portion **500** of kink-resistant gas delivery tube **400** of FIG. **4**, in which this first parameter is clearly visible. To illustrate this parameter, a number of definitions have to be initially made: An internal configuration **501** of tube **400** may be referred to as a parabola (or as a series of connected parabolic sections), where an apex **502***a* of a concavity **502** is a maximum point in a parabola, and apex **504***a* of convexity **504** is a minimum point in a parabola. A tangent line **502***b* to apex **502***a* and a tangent line **504***b* to apex **504***b* are shown. In between apexes **502***a* and **504***a*, the slope of the parabola constantly changes. A maximum slope point **506***a* of the parabola is where the value of the slope is maximal. A tangent line **506***a* to maximum slope point **506***a* is shown.

Advantageously, under these definitions, an angle α (alpha) between tangent line **504***b* and tangent line **506***a* is a sharp angle, shown here, by way of example, as an approximately 10 degree angle. In another embodiment (not shown), an angle α may be between approximately 5-15 degrees, while in yet another embodiment (not shown), an angle α may be between approximately 16-30 degrees.

Similarly, and also much advantageously, an angle β (beta) between tangent line **502***b* and tangent line **506***a* may be a sharp angle, shown here, by way of example, as an approximately 30 degree angle. In another embodiment (not shown), an angle β may be between approximately 5-15 degrees, while in yet another embodiment (not shown), an angle β may be between approximately 16-29 degrees.

Yet another advantage may be a ratio between angles α an β. In this figure, the ratio is approximately 1:3. In other embodiments (not shown), the ratio may be, for example, in the range of 1:1 to 1:4.5. It should be noted that the ratio is interchangeable, namely, it may be regarded as the ratio between α an β or between β and α.

It should be noted that in other embodiments (not shown), multiple, equal maximum slope points may exist, such as if multiple "waves" are present in the parabola between the maximum and minimum points. However, this need not change the specified, advantageous, angle ranges and ratio ranges.

A second parameter expressing the relaxed concave-convex configuration may be expressed by a relatively small difference in the wall thickness of the kink-resistant tube between the concavities and the concavities. Referring now back to FIG. **4**, a ratio between the wall thickness at concavities **402** and the thickness at convexities **404** is approximately 1:2. In other embodiments (not shown), the thicknesses may be different, and the ratio between them may be in the range of 1:1.25 to 1:3.

In an embodiment, an advantageous feature of tube **400** is the material from of which it may be made, and/or the thickness of the material. A relatively elastic material, such as soft polyvinyl chloride (PVC), may be used for making tube **400**. The PVC may be made soft by the addition of plasticizers during its manufacturing. The elasticity of tube **400** may enhance its ability to adapt to the circular shape of the nipple and create a gas-tight seal when manually pressed upon it. When pressure is applied on the internal structure of tube **400** by the circular nipple, this structure may stretch, pushing the areas of convexities **404** outside, so that an essentially circular internal shape of the tube is achieved, and an essentially gas-tight connection is formed.

Additionally or alternatively, the thickness of the walls of tube **400**, both at concavities **402** and at convexities **404** may be relatively low (although not equal, naturally), so as to allow the tube to better adapt to the circular shape of the nipple when manually pressed upon it. In this exemplary embodiment, the thickness of the wall at concavities **402** is approximately 0.4 millimeters, while the thickness at convexities **404** is approximately 0.8 millimeters, thereby enhancing the ability of the walls to stretch, pushing the areas of convexities **404** outside, so that an essentially circular internal shape of the tube is achieved, and an essentially gas-tight connection is formed. It should be noted that a diameter of exemplary tube **400** is approximately 6 millimeters. In other embodiments (not shown), where the diameter is smaller or larger, the wall thicknesses may decrease or increase, respectively. In yet further embodiments (not shown), the walls of the tube may have a different thickness than what is shown in FIG. **4**, such as a thickness in the range of 0.2 to 0.8 millimeters at the concavities and in the range of 0.4 to 1.6 millimeters at the convexities, respectively or irrespectively.

EXPERIMENTAL RESULTS

An experiment comparing the present kink-resistant gas delivery tube (such as tube **400** of FIG. **4**) with six common prior art tubes has been performed. The experiment has been conducted in accordance with sections 5.1.1 and 5.1.5 of European Standard No. EN 13544-2:2002E, which define, inter alia: (1) the maximum flow restriction created by the respective tube internal geometry; and (2) the minimum acceptable flow when a restriction (kink) is created. The results are shown in the table below:

Tube	(1) Resistance of tubing to gas flow (According to section 5.1.1 of the European standard) (in kPA/meter) Pass criteria max.: 0.9 kPa/meter	(2) Kink resistance of tubing (when tested According to section A6 of the European standard) (after 10 minutes, in Liters per minute, LPM) Pass criteria: 7.5LPM min.
Oxyplus OP-2000-8	0.41	8.5 LPM, 4 kPA
Salter 1600 TLC	0.35	10 LPM, 5.3 kPA
OXYMASK	0.41	9.5 LPM, 14.5 kPA
Capnoxygen CO2-04	0.45	9.5 LPM, 125 mBar 12.5 kPA
Airlite 001350	0.25	9.5 LPM, 9 kPA
Present tube	0.11	10 LPM, 4.6 kPA

As shown, the present tube passes both test criteria, while showing superior and remarkable performance in the flow resistance category. This may be explained by the direct correlation between the resistance to flow and the tube's internal surface area, due to friction between the gas and the tube's internal walls. The unique geometry of the present tube, with its relaxed concave-convex configuration, results in an internal surface area which is smaller than less relaxed configurations, where the stronger amplitudes are translated to an enlarged surface area. Therefore, the present tube may be especially advantageous in cases where the gas supply pressure is relatively low, since the tube will then allow much higher flow than tubes having less relaxed configurations.

While a number of exemplary aspects and embodiments have been discussed above, those of skill in the art will recognize certain modifications, permutations, additions and sub-combinations thereof. It is therefore intended that claims hereafter introduced be interpreted to include all such modifications, permutations, additions and sub-combinations as are within their true spirit and scope.

In the description and claims of the application, each of the words "comprise" "include" and "have", and forms thereof, are not necessarily limited to members in a list with which the words may be associated.

What is claimed is:

1. A kink-resistant gas delivery tube configured to be directly connected to a circular male plug, the tube comprising an internal geometry of a parabola having multiple concave areas each having an apex representing a maximum point of the parabola and convex areas each having an apex representing a minimum point of the parabola,

wherein an angle α between a tangent line to each of the apexes of the multiple concave areas and a tangent line to points of maximum slope of the parabola is 30 degrees or less, or

wherein an angle β between a tangent line to each of the apexes of the multiple convex areas and a tangent line to points of maximum slope of the parabola is 30 degrees or less; and

wherein said angle α and said angle β are configured to ensure that an essentially circular internal shape is achieved when pressure is applied on said internal geometry of said tube, such that a flow resistance of said tube is less than approximately 0.25 kPa/meter at a flow rate of 4 liters per minute.

2. The kink-resistant gas delivery tube according to claim **1**, wherein angle α is in the range of approximately 5-15 degrees.

3. The kink-resistant gas delivery tube according to claim **1**, wherein angle α is in the range of approximately 16-29 degrees.

4. The kink-resistant gas delivery tube according to claim **1**, wherein angle β is in the range of approximately 5-15 degrees.

5. The kink-resistant gas delivery tube according to claim **1**, wherein angle β is in the range of approximately 16-29 degrees.

6. The kink-resistant gas delivery tube according to claim **1**, wherein a ratio between angle α and angle β is in the range of approximately 1:1 to 1:4.5.

7. The kink-resistant gas delivery tube according to claim **1**, wherein a ratio between angle β and angle α is in the range of approximately 1:1 to 1:4.5.

8. The kink-resistant gas delivery tube of claim **1**, wherein said tube is configured to be directly connected to a circular male plug, the tube comprising an internal geometry of multiple concave and convex areas, wherein a ratio between a wall thickness of said tube at a concave area and a at convex area is in the range of 1:1.25 to 1:3; wherein said ratio is configured to ensure that an essentially circular internal shape is achieved when pressure is applied on said internal geometry of said tube, such that a flow resistance of said tube is less than approximately 0.25 kPa/meter at a flow rate of 4 liters per minute.

9. The kink-resistant gas delivery tube according to claim **8**, wherein said tube has an outer diameter of approximately 6 millimeters and a wall thickness of approximately 0.4 millimeters at a concave area and 0.8 millimeters at a convex area.

10. The kink-resistant gas delivery tube according to claim **1**, wherein said tube is made of soft PVC, wherein said soft PVC is made by addition of plastizer.

11. The kink-resistant gas delivery tube according to claim **1**, wherein less than approximately 0.25 kPa/meter at a flow rate of 4 liters per minute comprises approximately 0.11 kPa/meter at a flow rate of 4 liters per minute.

12. The kink-resistant gas delivery tube according to claim **1**, wherein less than approximately 0.25 kPa/meter at a flow rate of 4 liters per minute comprises between approximately 0.07 and 0.15 kPa/meter at a flow rate of 4 liters per minute.

13. The kink-resistant gas delivery tube according to claim **1**, wherein said tube, when kinked, enables a flow rate of approximately 7.5 liters per minute or more with a resistance less than 0.25 kPa/meter.

14. The kink-resistant gas delivery tube according to claim **13**, wherein approximately 7.5 liters per minute or more comprises approximately 10 liters per minute or more.

* * * * *